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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/898,736	07/23/97	COPPENS	T 61944
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IM22/0410

FITCH EVEN TABIN AND FLANNERY
SUITE 900
135 SOUTH LASALLE STREET
CHICAGO IL 60603-4277

EXAMINER

SHERRER, C

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 04/10/01

36

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/898,736

Applicant(s)

Coppens et al

Examiner

Curtis E. Sherrer

Group Art Unit

1761



☒ Responsive to communication(s) filed on Feb 14, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1, 3-9, 13-24, 27-31, 33, and 43-66 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 3-9, 13-24, 27-31, 33, and 43-66 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Part III DETAILED ACTION

Drawings

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Specification

2. The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification is not enabled for ATCC numbers 4858, 9363, 1891, 1472 and 14156. Because Claims 9, 24, and 28 require the organism, it is essential to the practice of the claimed invention. Therefore, applicants must comply with the deposit requirements set forth in 37 CFR 1.801 - 1.809. Specifically, Applicants need to provide an affidavit or declaration by applicant or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or of record over or her signature and registration number, stating that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent. See 37 C.F.R. 1.808 and MPEP 2404.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1- 9, and 48-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claims to recite the phrase “an amount of at least 1×10^2 per gram” and while the specification provides basis for this phrase is exist as a lower limit to a range. As the claim now reads, there is no upper limit to this range.

5. Claims 1, 3-9, 13-24, 27-31, 33, and 43-66 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants state in their specification and claims that spores can be activated by, among others, “addition of appropriate nutritional supplies (such as a nitrogen source, preferably amino acids and/or a carbon source, preferably mono- or disaccharides),” “exposure to temperature changes, preferably within a temperature range of 0 to 80C.” In the data presented in the Coppens Declarations, both of these steps were performed on claimed organisms without, according to applicants, activating the spores. Therefore, it appears that applicants are placing a heavy burden on those in the art to determine how to successfully activate spores.

6. In a preliminary response, found in Supplemental Declaration of Coppens, Paper #34 of 02/14/01, ¶ 19, applicants state that “together with the examples in my patent application, this

experiment illustrates that successful activation depends on incubation of dormant spore for a sufficient time at a suitable temperature and in a suitable medium.” Further, they have supplied two journal articles showing the activation of spores to support the enablement of the instant claims, whereby “one would know how to activate dormant spores, especially after reading the specification of the instant application.”

7. It is first noted that applicants claim to use the activated spores belonging to 96 genres of organism, which probably represent at least one thousand species of organisms and ten thousand subspecies. As guidance to those in the art on how to activate the spores of all these species, applicants have supplied two journal articles directed to only two species, and the instant specification, which is directed to one subspecies.

8. The Declaration shows that not just any of the disclosed methods might work to activate spores. Further, Ekundayo et al, one of the submitted references, shows, starting on page 264, that many variables will effect the activation process. Medwid et al, the other journal article, tested the effects of nine pH values, seven temperature values, five different types of media (with only one showing any activation), eleven different amino acids, four complex media, and forty two different carbohydrates. All this for one specie. To expect those in the art to perform this analysis for all the claimed organisms would be expensive, time consuming and with little guidance is to require undue experimentation.

9. Lastly, nothing on record has shown that the nature of the invention is well known. A search of the U.S. patent data base back to 1970 has revealed no patents that give specific guidance on how to activate specific spores.

Claim Rejections - 35 USC § 102/103

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 3-9, 13-24, 27-31, 33, and 43-66 are rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative rejected under 35 U.S.C. 103(a) as being unpatentable over Gyllang et al (European Brewing Convention (16th Congress)) for the reasons set forth in the last Office Action.

12. Applicants provide comments and data in their declarations that disclose that for the organism *Aspergillus fumigatis*, Pitt and Hocking (1997) shows that the condiospores dormant size is 2.5-3.0 microns in diameter. Further, Applicants state that "Our own observations of dormant spores of the three tested strains were in agreement with the description given by Pitt and Hocking (1997)." Supplemental Declaration of Coppens, ¶ 6, Paper #33 of 02/05/01. Applicants also state that "Activated spores were defined as described in the current patent

application as "being significantly more swollen than the dormant size, the size of the spores being increased by a factor preferably between 1.2 and 10 over the dormant spore size"

Supplemental Declaration of Coppens, ¶ 5, Paper #33 of 02/05/01. Therefore, for *Aspergillus fumigatis*, an activated spore would be in the range of 3 to 3.6 microns.

13. Applicants were informed that a more definitive showing, that the prior art did not teach activated spores, would be best done if the data for the spore size was submitted. Applicants did so in a more recent Supplemental Declaration of Coppens whereby data of the tests performed in the previous Supplemental Declaration of Coppens was provided.

14. A review of the data, submitted in the most recent Supplemental Declaration of Coppens, Paper #34 of 02/14/01, shows that a large majority of the *Aspergillus fumigatis* spores are in the activated range. It is noted that Coppens has modified his previous Supplemental Declaration to state that their observations of *Aspergillus fumigatis* dormant spores are actually the same size as the data now on record. This confuses the issue of anticipation at the very least. It would appear that the Gyllang spores are activated but for Coppens' new testimony. No reasons were given why the inventors now find that the spore size of *Aspergillus fumigatis* dormant spores has increased to actually cover the total range for the data now provided, where before the inventors were in agreement with the literature, which would indicate that the prior art spores are activated and therefore anticipate the claims. Until some explanation is given, it is assumed that the Gyllang spores are activated and therefore, the rejection is maintained.

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Response to Arguments

15. Applicant's arguments filed 02/01/01 have been fully considered but they are not persuasive for the reasons set forth above.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Sherrer whose telephone number is (703) 308-3847. The examiner can normally be reached on Tuesday through Friday from 6:30 to 4:30. The **fax phone number** for this Group is (703)-305-3602.

18. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



Curtis E. Sherrer
Primary Examiner
April 6, 2001